A hand wearing a blue nitrile glove holds a pink HbA1c test strip. The strip is positioned over a medical form that lists various tests. The test strip has a red tip and the text "HbA1c - Test" printed on it. The medical form includes sections for "Diabetes", "Renal Profile", and "Cardiovascular" tests, with checkboxes for each. The "HbA1c" checkbox is checked with a red mark.

THE GLUCOSE CONTROL MARKER HbA1c

Diabetes screening
Diabetes diagnosing
Glucose control monitoring

Why test HbA1c?

More than 500 million adults worldwide are affected by diabetes. The disease has taken a heavy toll on both health and the economy. Patients with diabetes have significantly higher risk of developing cardiovascular diseases and other health problems including nerve (neuropathy), eye (retinopathy) and kidney damages (nephropathy). Therefore, it is important to have a good marker for effective and efficient monitoring of diabetic control and diagnosis.

Unlike glucose level that fluctuates rapidly with food intake, exercise, and mental conditions, HbA1c level is more stable, and since its introduction in 1980s, has become the gold standard for monitoring blood glucose control and predicting glycaemia-associated risks.

Key numbers



537 million

537 million adults (1 in 10) have diabetes. This number is predicted to reach 643 million by 2030 and 783 million by 2045.



6.7 million

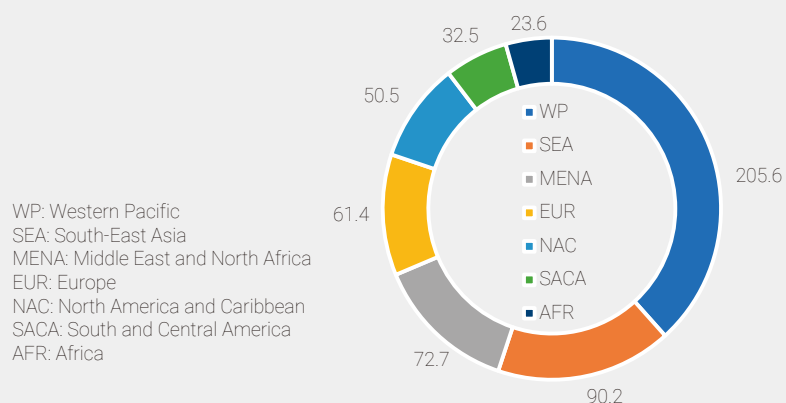
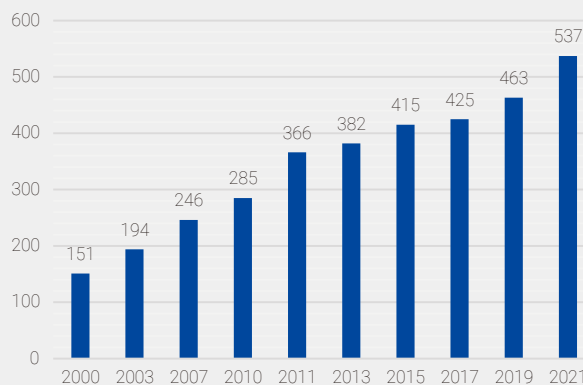
6.7 million people died from diabetes or its complications in 2021 - 1 every 5 seconds.



\$966 billion

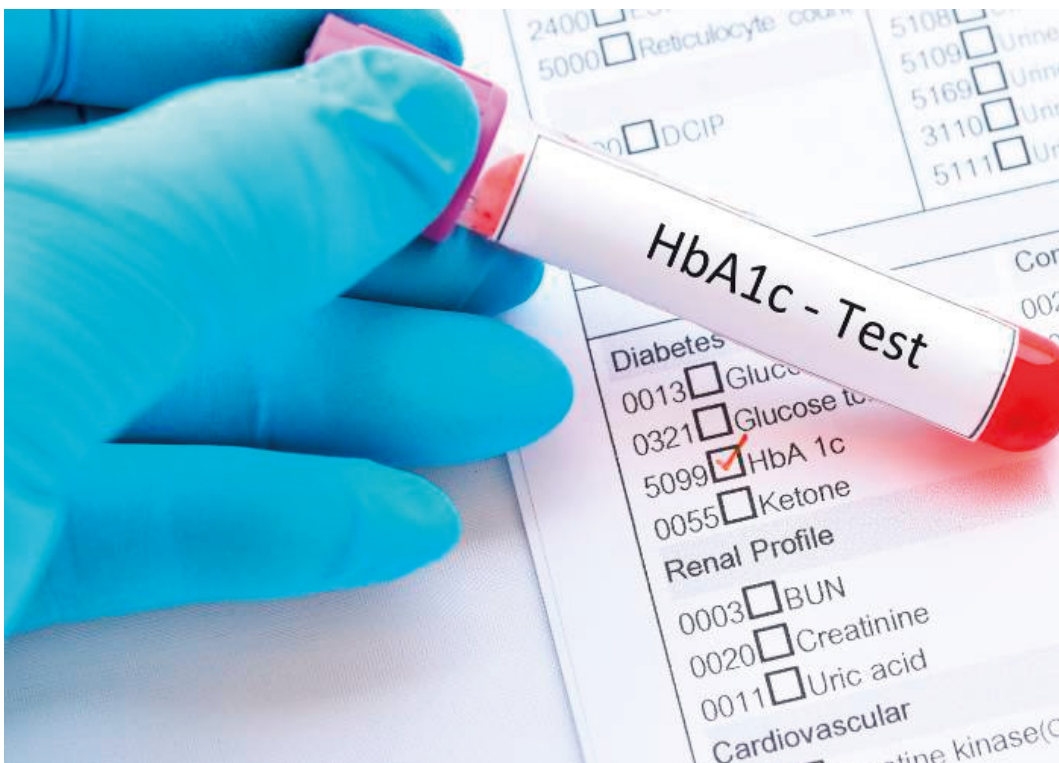
\$966 billion spent on diabetes in 2021 - a 316% increase over the last 15 years.

Estimates of the global prevalence of diabetes in the 20-79 year age group (millions)



What is HbA1c?

HbA1c, or hemoglobin A1c, is the product formed when glucose, the primary blood sugar, binds to the hemoglobin in your red blood cells. The process is a slow, continuous and non-enzymatic process that occurs during the life cycle of red blood cells, which is typically 2-3 months. As a result, the amount of HbA1c, expressed as the percentage of HbA1c, is directly proportional to the blood glucose level and serves as a marker to evaluate the average blood glucose level over the preceding 2-3 months.



When is HbA1c test ordered?

The HbA1c test is used to monitor the average blood glucose levels in individuals with diabetes and to aid in the treatment decisions. The test can also be used to help diagnose type 2 diabetes and to identify prediabetes. Effective blood glucose control is important in delaying, reducing and/or preventing the late diabetes complications, such as ketosis, retinopathy, nephropathy, etc.

HbA1c test is recommended to be performed twice a year for patients with diabetes. The HbA1c test may be performed more often in those who have just been diagnosed with diabetes, in those who have other health conditions, or when treatment plan changes, as recommended by the doctors.



What does the test result mean?

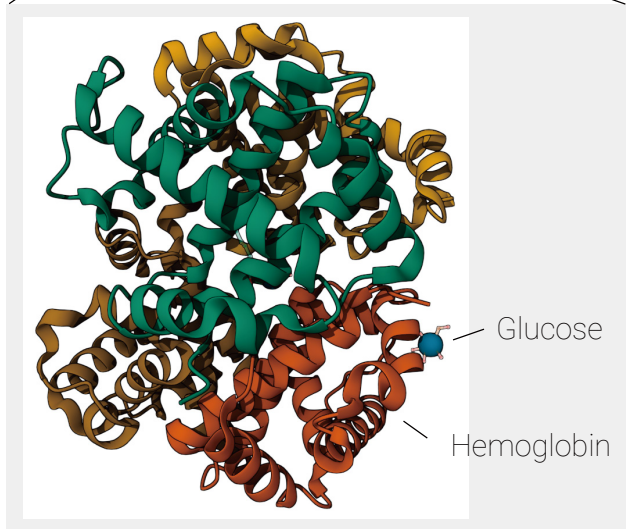
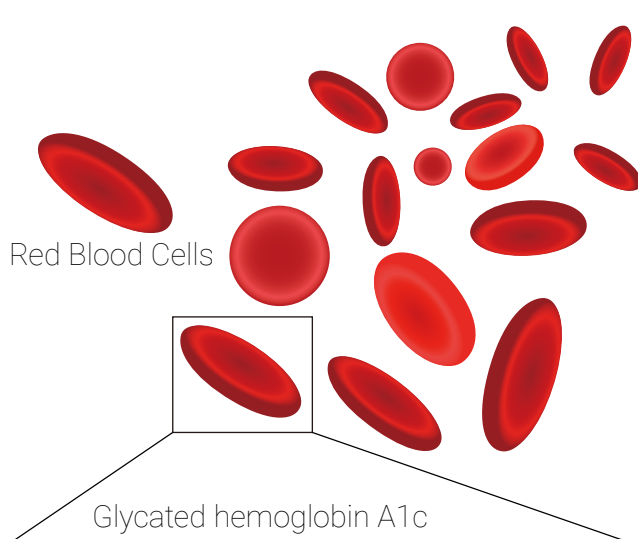
Like every diagnostic test, the test result of HbA1c is interpreted by comparing to the reference ranges while considering the clinical picture of the patient. A number of organizations have developed recommendations for HbA1c reference ranges. For example, the World Health Organization (WHO) recommended an HbA1c of 6.5% as the cut point for diagnosing diabetes. Some commonly cited reference ranges are provided below.

American Diabetes Association (ADA)			World Health Organization (WHO)		
NGSP unit	IFCC unit	Description	NGSP unit	IFCC unit	Description
<5.7%	<39 mmol/mol	Low risk/Normal			
5.7%- 6.4%	39- 46 mmol/mol	Risk of diabetes/Prediabetes	<6.5%	< 48 mmol/mol	does not exclude diabetes
≥ 6.5%	≥ 48 mmol/mol	Diabetes	6.5%	48 mmol/mol	cutoff point for the diagnosis of diabetes

Source:

Diagnosis and classification of diabetes mellitus. Diabetes Care, 2010; 33 Suppl 1:S62-S69

World Health Organization. Use of glycated haemoglobin (HbA1c) in the diagnosis of diabetes mellitus: abbreviated report of a WHO consultation. WHO, 2011.

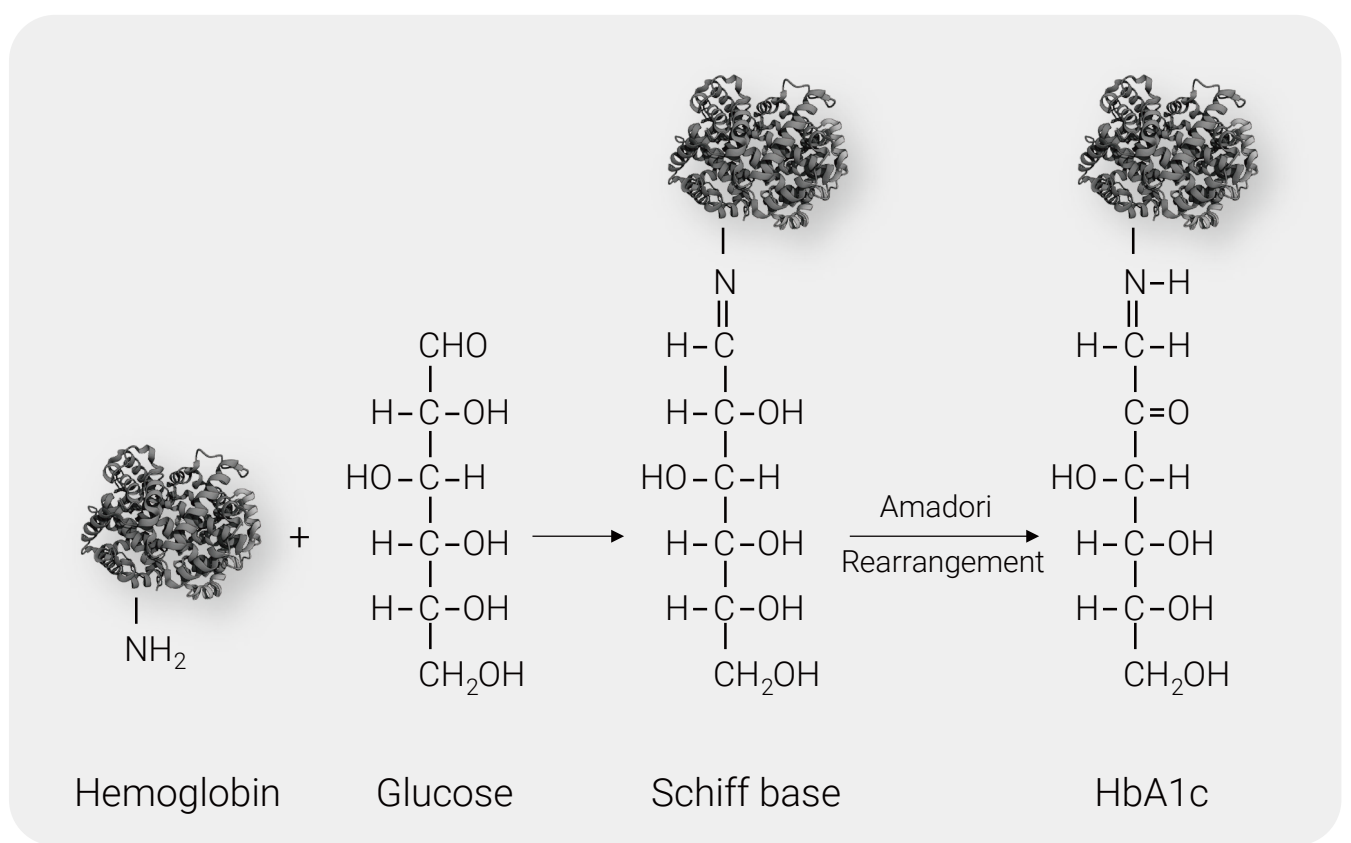


HbA1c is formed when glucose attaches posttranscriptionally and nonenzymatically to the N-terminal valine amino acid of the β chain of the hemoglobin molecule (Hb).

The image was created by Mol* Viewer using PDB ID 3B75.
For illustration purpose only.

Peterson, K. P., et al. What is hemoglobin A1c? An analysis of glycosylated hemoglobins by electrospray ionization mass spectrometry. Clinical Chemistry, 1998; 44(9): 1951-1958.

Figure 1 Illustration of HbA1c formation.



“

Intensive therapy (normoglycaemia and an HbA1c of <6%) effectively delays the onset and slows the progression of diabetic retinopathy, nephropathy, and neuropathy in patients with IDDM (insulin-dependent diabetes mellitus). ”

The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med, 1993; 329: 977–86.

“

A strategy of intensive glucose control, involving gliclazide (modified release) and other drugs as required, that lowered the glycated hemoglobin value to 6.5% yielded a 10% relative reduction in the combined outcome of major macrovascular and microvascular events... ”

Intensive blood glucose control and vascular outcomes in patients with type 2 diabetes. N Engl J Med, 2008; 358: 2560–2572.

“

Lack of standardization of HbA1c determinations prevented optimal use of the test; studies had clearly shown the advantages and feasibility of standardizing HbA1c assays. Both NGSP (National Glycohemoglobin Standardization Program, reports HbA1c in %) and IFCC (International Federation of Clinical Chemistry and Laboratory Medicine, reports HbA1c in mmol/mol) have established laboratory networks to standardize the HbA1c results.

Continuous monitoring within NGSP and IFCC annually allows harmonization of HbA1c results world wide. ”

Ang, S. H., et al. Current aspects in hemoglobin A1c detection: a review. Clinica chimica acta, 2015; 439: 202-211.

“

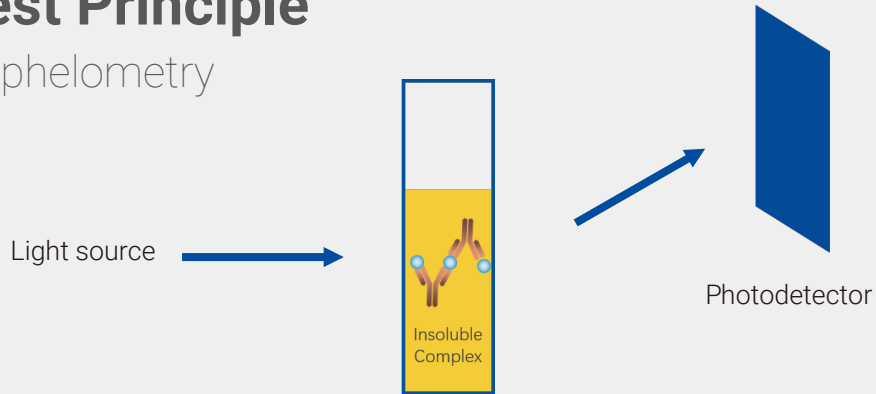
Nephelometry and IECR both had better performance and showed a greater concordance with gold standard HPLC. Therefore, nephelometry and IECR can be used as an alternative assay for HbA1c estimation. ”

PRATHIMA, M. B., et al. Estimation of Glycated Haemoglobin by Nephelometry, Ion Exchange Resin and High Performance Liquid Chromatography: A Cross-sectional Study. Journal of Clinical & Diagnostic Research, 2020; 14(9).

Flagship Assay on GPP-100 with Excellent Performance

Test Principle

Nephelometry



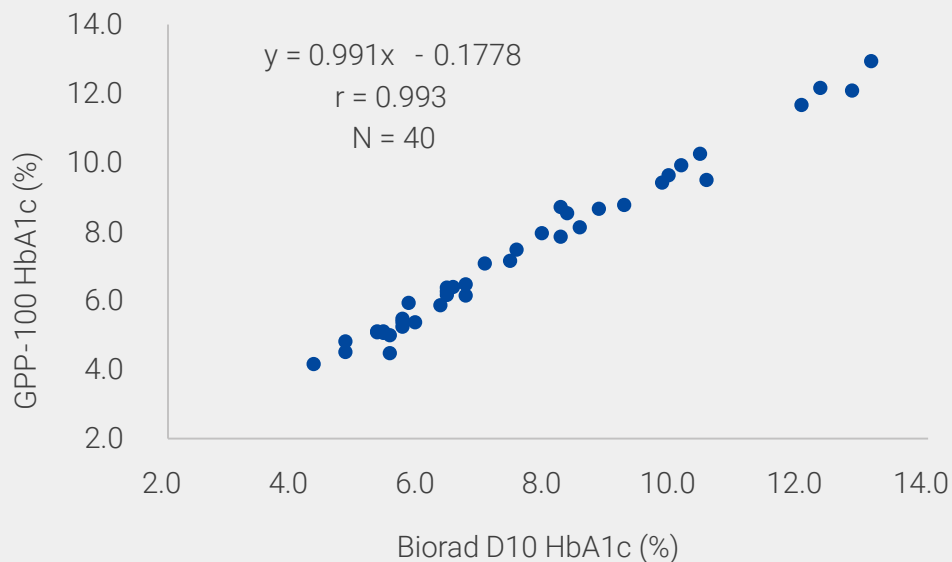
NMPA approved

 certified

 certified
International Federation
of Clinical Chemistry
and Laboratory Medicine

 marked

Method Comparison with HPLC



GPP-100 Technical Specifications

Measuring time	3 to 8 minutes
Sampling material	Whole blood, serum, plasma, urine
Test principle	Nephelometry
Sample volume	3 µL to 300 µL
Data storage	Up to 100,000 test results
Power	100 – 240 VAC, 50/60 Hz, 90 VA
Display	Color touch screen
Printer	Built-in thermal printer
Weight	7.1 kg
Physical dimensions	404 mm * 161 mm * 397 mm



GPP- 100 HbA1c Kit Specifications

Analyte	Sample type	Measuring time	Linear range	Storage	Shelf life
HbA1c	Whole blood (capillary blood or Venous blood with EDTA)	8.5 min	2.8%–15.50%	2 – 8°C	12 months

Ordering information	Catalog number	Pack size
Analyzer		
Specific Protein Analyzer	GPP-100	1 unit
Reagent Kit and Controls		
GPP- 100 HbA1c Kit	GP72020	20 tests
HbA1c Control	HBDM072	0.5 mL
HbA1c Control High Level	HBDM072H	0.5 mL

Expertise on IVD
Since 1999

GOLDSITE
Goldsite Diagnostics Inc.

📍 No. 1001, Building No.1,
Goldsite Technology Building,
No. 9 Rongtian Road,
Pingshan District,
Shenzhen, China, 518122

☎ 0086 755 2689 0807
✉ export@goldsite.com.cn
🌐 www.goldsite.com.cn

   
@ Goldsite Diagnostics